Information Technology Initiatives in Drug Registration Submissions

Case Study: Exelon™

Krishan K. Arora, PhD

Novartis Pharmaceuticals Corporation

Washington DC, January 13, 1998

NOVARTIS

Why E-submission?

- Exelon^{TM} Cholinesterase Inhibitor for the Treatment of Alzheimer's Disease

- Size and complexity
  - ~3600 Pats, ~500 Vol, ~600 Vol CRFs in US & UK
  - Reports authored in US, UK, Switzerland

- Had developed a good concept ESs

- Goal to remain among the leaders, and file one E-format worldwide

NOVARTIS

Difficulties/Solutions

- **No Elec. doc. mgt. and pub. system**
  - Centralize preparation
- **No extra time for E version(s); different formats in Europe, US and Canada**
  - Negotiate with agencies
- **Limited in-house expert resources**
  - Outsource to able and reliable parties
  - Merger: a difficulty but also helpfull
- **Last minute changes:** no solution? Just do it!

Agency Help: CDER + EU

- **Proposals and test samples of CRFs, Reports and Data to FDA,** began April '96
  - FDA - 11/25/96: PDF images, PDF, JMP datasets
  - Extensive links and bookmarks for easy browsing
- **Agreements with other agencies**
  - EMEA - 1/21/97: PDF (Part I)
  - AdM - 1/23/97: PDF (Part I+Clin), HW, 2 Wks
  - MPA - 1/21/97: PDF, (Part I+Clin) HW, 2 Wks
  - HPB - 2/13/97: PDF, HW, 4 Wks

NOVARTIS

Lessons Learned

◆ Plan and begin early: 12-15 months

◆ Be innovative: but stay within standards

◆ Be flexible: negotiate, negotiate, negotiate

◆ Lay your cards on table; discuss your limitations: get reviewers' attention

◆ Collaborate with agencies: keep promises

NOVARTIS

Do it again? Benefits?

- Yes
- Save time and money
- Facilitate dev and review in-house
- Facilitate communications (Q&A)
- Increase IT capability
- Moving to paperless environments
- Necessary and the Right thing to do! Year 2002!!

Think Key Elements Not TOC

- **Text:** Word/ WordPerfect Documents: PDF
  - Legacy reports: PDF Images

- **Listings and tabulations:** PDF

- **Data:** raw/derived data: open
  - Table of dataset names: links to data files

- **CRFs/CRTs and Graphics:** PDF Images

- **Browsing:** Extensive Hyperlinks and bookmarks